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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,018	05/29/2001	Neil Roberts	ST 98027	1295

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EXAMINER

GUO, LYND A T

ART UNIT PAPER NUMBER

1651

DATE MAILED: 10/25/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/763,018	<b>Applicant(s)</b> ROBERTS ET AL.	
	<b>Examiner</b> Lynda T Guo	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2001.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Status of the Application*

The Change of Address (Paper No. 6) received on 28 February 2002 has been entered.

Claims 1-9 are pending in the present application.

### *Specification*

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and **legal phraseology** often used in patent claims, such as "means" and "said," **should be avoided**. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because legal terminology used. Correction is required. See MPEP § 608.01(b).

3. A review of the present Specification does not show a single invention. For example:

Page 1 of the present Specification suggests the invention solved the following problems:

- 1) A method "to check the uniformity of distribution of the enzymes added to the feed;
- 2) A method "to quickly and easily evaluate the activity of the enzyme(s) added to the feeds.

Page 3 of the said Specification teaches on the measurement of enzymatic activity. However, the Figures show an apparatus (i.e. the graduated funnel).

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Therefore, no singular point of novelty is seen. What is searched and considered here are 1) a container and 2) a method for determining enzymatic activity in a container with a reagent and buffer.

4. The disclosure is objected to because of the following informalities:

The various sections of the present Specification are not clearly labeled or separated by the appropriate headings. Below are the guidelines for the proper arrangement of a specification.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.

- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-9 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Following are a list of phrases in the aforementioned Claims which lack antecedent basis: "the test sample", "the enzyme", "the said enzyme", "the liquid", "the substrate", "the coloration", "the column", "the stopper". Applicant is reminded that usage of "the" and "said" need to have proper antecedent basis for their usage.

Claim 1 is vague and indefinite in that no specific enzyme is claimed.

In Claim 7, "the buffer used to measure" lacks antecedent basis since it is dependent on Claim 1, which recites only of "a buffer for dissolving".

In Claim 9, it is unclear as to what the "specific buffer" is specific to. It is also unclear as to how the liquid phase is separated and recovered.

***Claim Rejections - 35 USC § 101***

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 8 is drawn to a use of the claimed device and thus does not qualify as statutory subject matter (i.e. process, machine, manufacture or composition of matter).

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

9. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Bio-Rad Laboratories, Inc.

Claims 1-7 is drawn to a device for measuring enzymatic activity of a sample. Claim 1 recites that the device is comprised of “a container **designed** to contain a test sample, a reagent...and a buffer”. Only Claims 3 and 4 further define the dimensions of the container, all other claims

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(Claims 2, 5-7) are drawn to components that the container is **intended** or **“designed”** to hold and thus does not further limit Applicant’s invention (i.e. “container”).

As recited by Claims 3 and 4, the claimed invention is a “graduated column or tube fitted with a leakproof opening and closure system” and it further comprises “a cleavable protuberance at its base”.

According to Bio-Rad Laboratories, Inc., a column (Econo-Pac Column) has been commercially available since at least 1993 (see picture in the Bio-Rad 1993 Catalogue, page 62 and the figure from the company’s website). The Econo-Pac Column is graduated with an attached end cap (i.e. “opening and closure system”) and a snap-off tip (i.e. “cleavable protuberance”) at its base. Also available is the Poly-Prep Column, which has similar features, both are disposable. The said columns thus encompass all the limitations of Applicant’s invention, which is thus rejected.

10. Claim 9 is rejected under 35 U.S.C. 102(e) as being anticipated by Michelsen et al. (USPN 6,143,543).

NOTE: A recent copy of the protocol for Xylazyme Tablets (obtained online from [www.megazyme.com](http://www.megazyme.com)) is used for this present Office Action and is assumed to be equivalent to the protocol as recited by USPN 6,143,543.

Claims 9 is drawn to a process of measuring enzymatic activity in that sample is introduced into a container (Applicant’s claimed invention as according to Claim 1) along with a solid reagent and buffer. The liquid phase of the reaction is then separated from the solid and the intensity of the liquid phase is measured.

Michelsen discloses the measurement of xylanase using Xylazyme Tablets (from Megazyme) according to manufacturer’s recommended conditions. This includes mixing the enzyme sample

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with buffer and the solid reagent (Xylazyme Tablet) and then separating the liquid from the solid via filtration and then color is measured at absorbance of 590 nm. (See Column 20, Lines 8-17 of USPN 6,143,543 and Page 6, Assay Procedure of Megazyme protocol.)

Therefore, all of the limitations of Claim 9 have been fully anticipated by Michelsen and are thus rejected.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda T Guo whose telephone number is (703) 605-1200. The examiner can normally be reached on Mon - Fri (8:00am - 4:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lynda T Guo  
Patent Examiner  
October 24, 2002



RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200